

APPROVED



UNITED STATES
DEPARTMENT OF
AGRICULTURE

AGRICULTURAL
MARKETING
SERVICE

LIVESTOCK AND
SEED PROGRAM

Washington, D.C.
20250-0254

TECHNICAL

REQUIREMENTS

SCHEDULE – BB - 2005

FOR USDA PURCHASES OF

**FRESH-CHILLED BONELESS BEEF
FOR FURTHER PROCESSING**

**EFFECTIVE:
APRIL 2005**

Preparing Activity:
USDA, AMS, LS, STDZ--Rm. 2607-S
Supersedes TRS-BB-May 2004
Changes are in *Blue Italics*
APRIL, 2005 – Draft for Discussion Purposes
LS-SB-TRS-BB-04-R2-SCO

I. SCOPE

This Technical Requirements Schedule (TRS)–BB–2004 is for use by a contractor of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Livestock and Seed Program (LS) to deliver fresh-chilled (never previously frozen) boneless beef for further processing.

II. APPLICABLE DOCUMENTS

The Audit Review and Compliance (ARC) Branch Procedures, Series 1000.

III. CHECKLIST OF REQUIREMENTS

The contractor's technical proposal must describe a process plan with a documented quality control program that includes procedures, records, forms, etc. that demonstrate conformance with the following Checklist of requirements.

A. MATERIAL REQUIREMENTS FOR FRESH-CHILLED BONELESS BEEF

1. Domestic Origin and Harvest (Slaughter) Requirements – Boneless beef shall be derived from cattle harvested at facilities that comply with the following origin and harvest requirements.
 - a) Domestic Origin - All beef will originate from U.S. produced livestock *as defined within Announcement LS -121*.
 - b) Humane Handling - All cattle shall be humanely handled in accordance with all applicable FSIS regulations, directives, and notices.
 - c) Non-Ambulatory Disabled Cattle – Meat from carcasses of non-ambulatory disabled cattle will not be included in USDA purchased boneless beef for further processing.
 - d) Spinal Cord Removal – Remove all spinal cord tissue during the harvesting process.
 - e) Pathogen Intervention - Include at least two pathogen intervention steps. One of the intervention steps shall be steam pasteurization, an organic acid rinse, or a 180°F hot water wash and must be a critical control point (CCP) in their FSIS recognized slaughter process Hazard Analysis Critical Control Point (HACCP) plan.
 - f) Carcass Testing - Routinely test carcasses for *E. coli* O157:H7 at CCP to verify effectiveness of interventions, as provided in Section VI. B. 3 of FSIS Directive 10,010.1 dated 2-1-98.
2. Boneless Beef Requirements
 - a) Lot – For the purpose of this section, a lot shall consist of boneless beef produced between “*cleanup to cleanup*” and that is from a single slaughterer or from a single processor. *Lot size will be a minimum of approximately 10,000 pounds*.
 - b) Traceability – *Boneless beef shall be traceable to sources that comply with the above domestic origin and harvest requirements*.
 - c) Handling - All boneless beef must be maintained in excellent condition. The contractor's technical proposal shall include detailed production scheduling that addresses time and temperature controls necessary to maintain excellent condition of the boneless beef.

- d) Objectionable Materials - *The following objectionable materials shall be excluded:*
- (1) Major lymph glands (prefemoral, popliteal, and prescapular), *thymus gland*, bone, cartilage, *sciatic (ischiatric)* nerve (from the round), internal fat (kidney, pelvic, and heart fat).
 - (2) All bone, cartilage, and the following heavy connective tissues:
 - (a) White fibrous – Shoulder tendon, elbow tendon, silver skin from the outside round, *sacrociatic* ligament, opaque *periosteum*, *serous* membrane (*peritoneum*), tendinous ends of shanks, *patellar ligament (stifle joint)*, *gracilis* membrane (from the inside round), and *achilles* tendon.
 - (b) Yellow elastin – Back strap and *abdominal tunic*.
- e) Microbial Testing – All lots of fresh chilled boneless beef must be tested for all microbes listed in Appendix B. For this section, all samples will be sent to an AMS designated laboratory (ADL).
- (1) Sample Preparation – From each lot (*minimum of 10,000 pounds*), *sample units* (of approximately equal size) *will be selected from approximately 2,000 pound increments and made into* a composite sample. *The sample units shall include meat surface tissue from intact cuts of beef. The composite sample shall be* ground/chopped and blended together *in an aseptic environment. When boneless beef has been exposed to any anti-microbial treatment, no sample units shall be selected for at least 15 minutes after such treatment.* A single sample shall be drawn from this mixture and submitted for analysis. The ADL will be responsible for supplying all materials, protocol and methods (including *size of the sample*, handling, reserve samples, etc.) for sample preparation and submission.
 - (2) Testing and Results - The sample will be analyzed by the ADL for microbial levels listed in Appendix B.
 - (a) The microbial test for all microbes, except for *E. coli O157:H7*, will be in accordance with the applicable test methods listed in the Compendium of Methods for the Microbiological Examination of Foods (current edition), published by the American Public Health Association.
 - (b) The presence of *E. coli O157:H7* will be determined using test methods that are within or conform to the "USDA/FSIS Microbiology Laboratory Guidebook (http://www.fsis.usda.gov/Science/Microbiological_Lab_Guidebook/index.asp), Chapter 5.03" for Detection, Isolation, and Identification of *Escherichia coli O157:H7* and *O157:NM* (Nonmotile) from Meat Products, Effective Date 10/25/02.
 - (c) *FSIS Notification for presence of pathogens - When presence of E. coli O157:H7 or salmonella is positive:*
 - (i) *The ADL will notify FSIS.*
 - (ii) *FSIS will be notified by the boneless beef supplier for final disposition of the product.*
 - (iii) *The contractor shall conduct a cause and effect analysis to determine the appropriate corrective action necessary to eliminate the probable cause. The corrective actions must be implemented and proven effective.*

- (d) The ADL will record and plot the results on control charts and histograms for each microbial test (as illustrated in Appendix A and further defined in Appendix E). The control charts and histograms will be maintained so that process capability may be determined according to the requirements within Appendix B.
- (3) Requirements – The capability of a boneless beef supplier to comply with microbial requirements will be based on assessment of control charts and histograms. Test results will be monitored by the contractor and AMS to determine process capability according to Appendix B.
- (4) *Contractor's Responsibility - The boneless beef supplier will notify the Contracting Officer and will direct the ADL regarding charting and computation needs due to any change in status. In the event a boneless beef supplier has been deemed ineligible, and wants to continue in the program, the ineligible boneless beef supplier must first provide the Contracting Officer their plan to implement corrective actions. Once the plan is agreed to by Contracting Officer, then the boneless beef supplier must receive a satisfactory onsite assessment audit from AMS. Upon notification by the Contracting Officer that the plan has adequately addressed the issues that resulted in the ineligible status determination the boneless beef supplier may reenter the program.*

B. STATE OF REFRIGERATION

Fresh-chilled boneless beef shall be maintained and delivered at a temperature not to exceed 40°F.

C. FAT LIMITATIONS

1. Requirements - The contractor will establish a target average of 15 percent fat of all boneless beef destined for all USDA destinations. The upper and lower specifications limits will be 18.0 and 12.0 percent fat respectively. Production lots with average fat results that are not within the upper and lower specification limits will not be shipped to USDA.
2. Process Capability -The processors capability (Cpk) value shall be 1 or higher when the average results from twenty consecutive production lots (which always will include the last production lot) are calculated.
3. Documentation - The contractor shall declare within their technical proposal:
 - a) Lot size, number of samples, selection and preparation procedures,
 - b) The laboratory and a test method,
 - c) Data management and storage of fat results,
 - d) Statistical Process Control (SPC) charting methods which will include a process capability report (histogram) that is capable of calculating a Cpk value (see exhibit A).
4. Assessment by AMS - AMS reserves the right to:
 - a) check production records of the recipient where the contractor's boneless beef is further processed;
 - b) select and analyze samples at the further processor. The results may be used by the contracting officer as a "check" to determine if fat content is in compliance with the fat limitation requirements; and/or
 - c) deem a supplier as unreliable for failure to comply with the above requirements.

D. PACKAGING AND PACKING

The contractor's technical proposal and process will assure that all packaging, packing, closure, marking and palletization comply with the National Motor Freight Regulations and FSIS regulations and the requirements listed below. The contractor also must have procedures for verifying the net weight of shipping containers.

1. Packaging and Packing – The contractor shall bulk package the boneless beef within lined “combo bins” in such a manner to maintain the product in excellent condition. The combo bins of boneless beef shall be sealed so that the container is tamper proof and arrives at the destination intact.
2. Net Weight – The contractor shall have procedures that accurately determines the net weight of the boneless beef. Each filled combo bin shall weigh from 1850 to 2250 pounds. AMS reserves the right to perform net weight examinations at destination.
3. Marking of Containers – All shipping container markings shall include all information required by FSIS regulations and the following information:
 - a) “Complies with TRS – BB 2005 - Boneless Beef for Further Processing”:
 - b) A code number that will indicate traceability to production lot and date.
 - c) USDA Shield (at least 2 inches high).
 - d) Contract Number.
 - e) Fat Declaration.
 - f) Product code - A704

All labeling shall be illustrated in the Contractor's technical proposal.

4. Total net weights per delivery unit - The delivery unit will be 40,000 pounds.

IV. CONTROL OF NON-CONFORMING PRODUCT

The contractor must include a plan to assure that non-conforming product is not delivered under USDA contracts. The plan must address 1) control and segregation of non-conforming product, 2) removal of any USDA markings, and 3) disposition of non-conforming product.

V. QUALITY ASSURANCE

A. Warranty and Complaint Resolution -

1. Warranty – The contractor will guarantee that the product complies with all contractual requirements.
2. Complaint Resolution – The contractor's technical proposal must provide the steps taken to resolve complaints received on the product i.e, point of contact, cause and effect analysis, corrective and preventative actions taken, and product replacement.

B. Checkloading – Invoice for payment must be supported by:

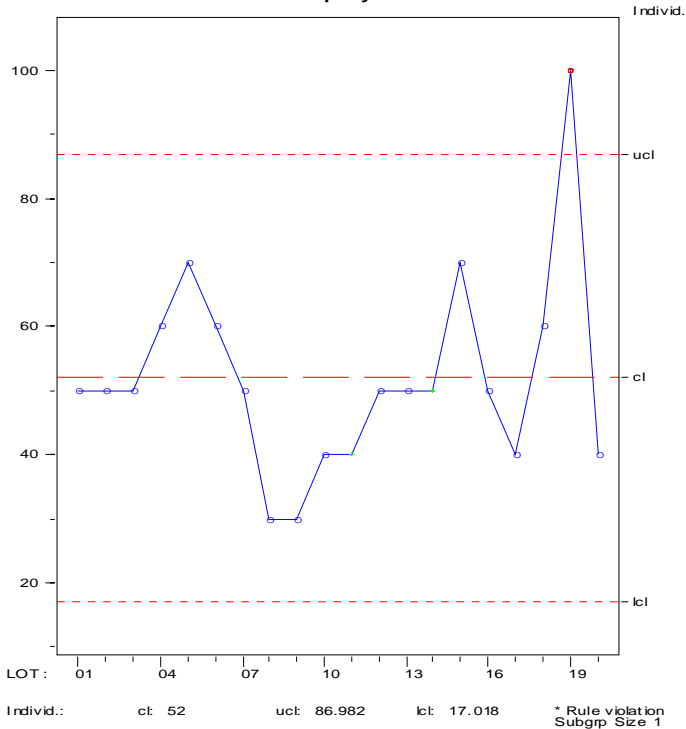
1. a recipient's signature on the bill of lading;
2. a consignee's receipt evidencing date shipped and received; or
3. other commercial receipt evidencing delivery of the product.

APPENDIX A

Example Statistical Process Control Charts and Histograms

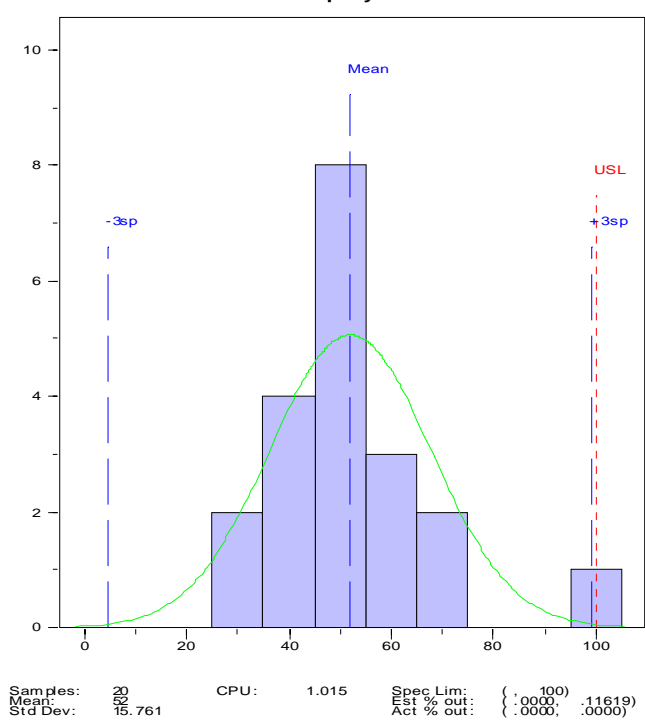
Control Chart

AMS Microbial Data
Generic E. coli
Company = A



Histogram

AMS Microbial Data
Generic E. coli
Company = A



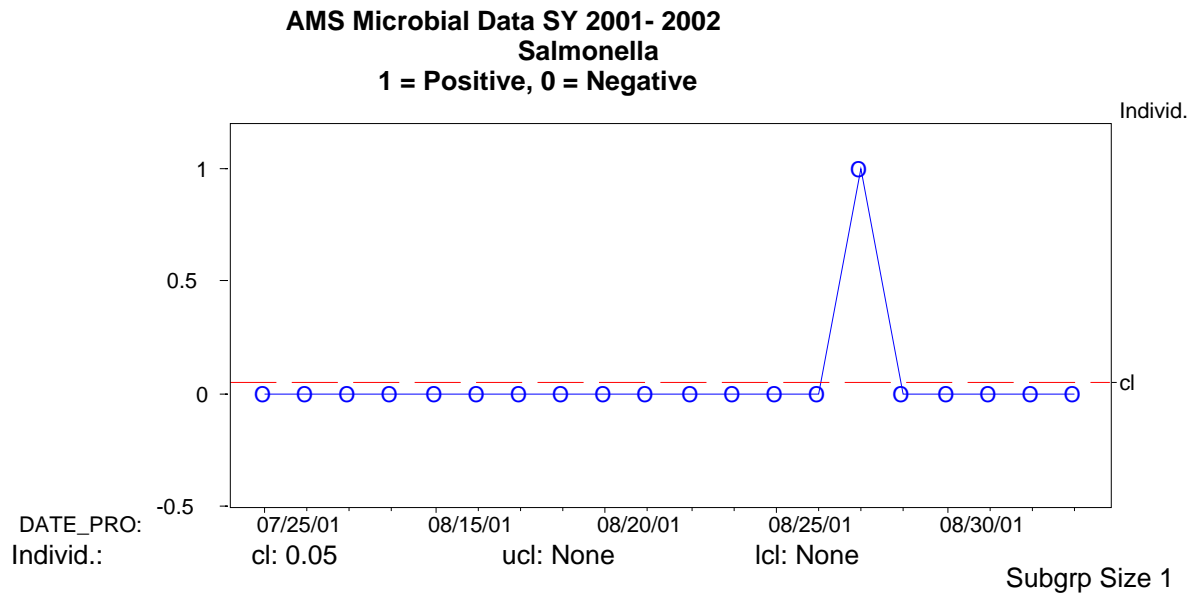
The above control chart and histogram are examples for illustrative purposes.

The control chart will have statistically derived upper control limits (ucl) and lower control limits (lcl) (+/- 3 times the standard deviation of the process average), and the central line (cl) value (process average, mean or x-bar). Since the subgroup size for microbial test is one (1), the calculation for standard deviation will be on individual measures. *For data entry purposes, when microbial test results are preceded with < (less than) symbols preceding the values, the value to be entered will be the number minus one (i.e., "<10" will be entered as "9"; "<2500" will be entered as "2499").*

The process capability value (C_{pk} or C_{pu}), is below the histogram chart (capability report). Since there are no lower specification limits within USDA microbial requirements, the C_{pu} will be used. The C_{pk} will be used for fat requirements that have a lower and upper specification limit. The applicable upper specification limits (USL) along with the capability limits (+/- 3 times the standard deviation of the individual measures (+/- 3sp)) will be displayed within the histogram. USL for microbial requirements will be found in Appendix B and Appendix C. The calculation for the C_{pu}/C_{pk} for microbial and fat requirements involves two steps:

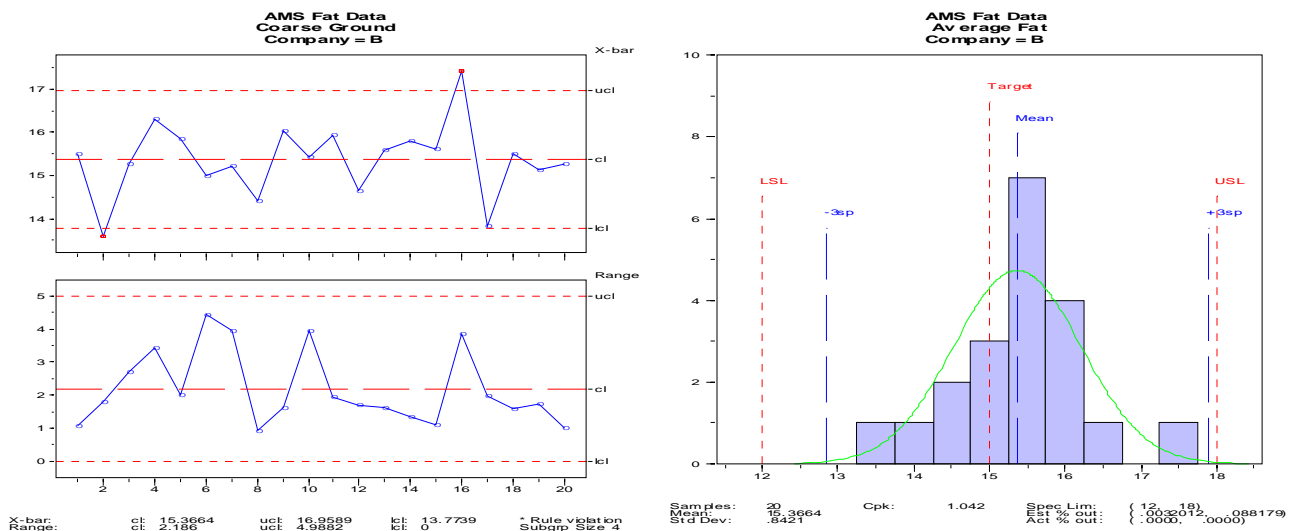
Calculation of C_{pu} with an upper specification limit only	
Step 1. The first calculation will determine the z value:	Step 2. The Z value divided by 3 will calculate the process capability (C_{pu}).
$Z \text{ value (upper)} = \frac{USL - \text{Process Average}}{\text{Standard Deviation of individual measures}}$	$C_{pu} = \frac{Z \text{ value (upper)}}{3}$
Calculation of C_{pk}	
Step 1. The first calculation will determine the min z value:	
$Z \text{ value (upper)} = \frac{USL - \text{Process Average}}{\text{Standard Deviation}}$	$Z \text{ value (lower)} = \frac{\text{Process Average} - LSL}{\text{Standard Deviation}}$
Step 2. The min Z value divided by 3 will calculate the process capability (C_{pk}).	$C_{pk} = \frac{Z \text{ value (min)}}{3}$

Control Chart



The central line (cl) in the above control chart indicates the incidence of positive *Salmonella* results (5.0%). The results are plotted with the positive results for *Salmonella* as 1 and negative results as 0.

The charts below are illustrative of the x-bar and range control charts and a process capability report (histogram) that may be used to measure fat content performance of the boneless beef supplier. For the boneless beef purchase program, the target must be 15 and the upper and lower specification requirements must be 18.0 and 12.0 percent fat respectively.



APPENDIX B

AMS BONELESS BEEF PROCESS REQUIREMENTS FLOW CHART

Quality Control Program – Prior to supplying boneless beef destined for USDA, the boneless beef supplier must submit a documented quality control program and receive a satisfactory onsite capability assessment by the ARC branch. *The quality control program must specifically address management of microbial data to comply with AMS Process Requirements Flow Chart and following descriptions.*

Process Assessment Status - A process assessment involves sampling and testing of 20 consecutive lots (*which always includes the last recorded result as defined in APPENDIX E*) of boneless beef destined for USDA ground beef *for the microbes listed in the table below. Boneless meat may be shipped for further processing prior to receipt of test results. However, production lots of further processed beef containing the involved boneless beef lots that have positive results for Salmonella and E. coli O157:H7 will be rejected.*

Process Capable? – *Flow chart decision step that involves* test results for 20 consecutive lots (which will include the last recorded result) plotted on control charts and histograms (See APPENDIX A) *for evaluation. A process that is not capable shall be declared to the contractor immediately when results are known and will result in switching from process assessment status to conditional status or switching from conditional status to ineligible status when:*

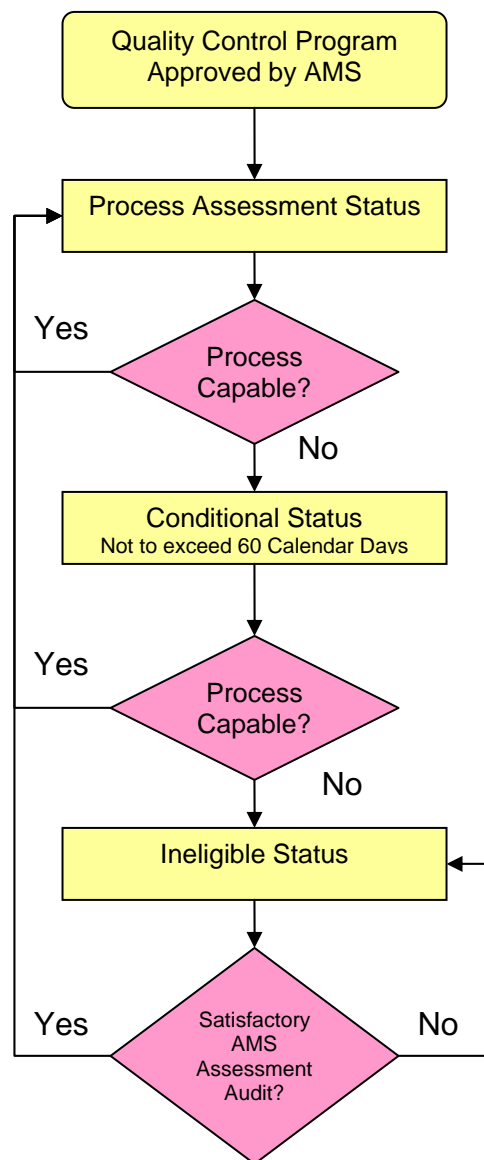
- The central line (CI) *value or the* process capability value (CPU) does not meet the levels specified in the table below.
- *Two results exceed any of the critical limits in the table below; * or*
- The CPU value after 2 or more results is negative.*

** - Immediate action will be taken prior to completion of 20 lots.*

Conditional Status – Boneless beef production lots with test results that *meet or* exceed any of the Critical Limits listed in the table below may not be used in ground beef that is delivered to USDA. To regain process assessment status, the boneless beef supplier and/or the contractor must have 20 consecutive results that meet the **‘Process Capable?’ criteria** within 60 calendar days *or in accordance with a production schedule pre-approved by the Contracting Officer after successfully implementing corrective actions. A boneless beef supplier may declare itself as ineligible at any time.*

Ineligible Supplier/Contractor – An Ineligible Boneless Beef Supplier will not be allowed to supply boneless beef to any USDA contracted grinding facilities until corrective actions have been implemented, proven effective, and a satisfactory AMS assessment audit has been completed. *At any time, the Contracting Officer may declare a boneless beef supplier ineligible.*

AMS PROCESS REQUIREMENTS FLOW CHART



AMS MICROBIAL REQUIREMENTS FOR BONELESS BEEF TABLE

Microbial Test	Upper Specification Limits	Critical Limits	CI or CPU Value
Standard Plate Count	100,000/gram	500,000/gram	$CPU \geq 1$
Total Coliforms	500/gram	2,500/gram	$CPU \geq 1$
<i>E. coli</i>	100/gram	1,000/gram	$CPU \geq 1$
<i>Salmonella</i>		Positive Results/25 grams	$CI \leq 0.05$
<i>E. coli</i> O157:H7		Positive Results/325 grams	$CI \leq 0.05$

APPENDIX C

Glossary of Terms

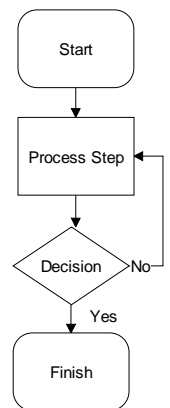
Statistical Process Control (SPC) – SPC is the primary analysis tool of quality improvement. The objective of any quality improvement strategy is to identify and reduce the amount of variation. SPC analyzes the variation in a process and is the applied science that assists suppliers to collect, organize and interpret microbial and fat test results on processing of ground beef destined for USDA.

SPC provides tools to help measure, identify, and eliminate variation from customer requirements.

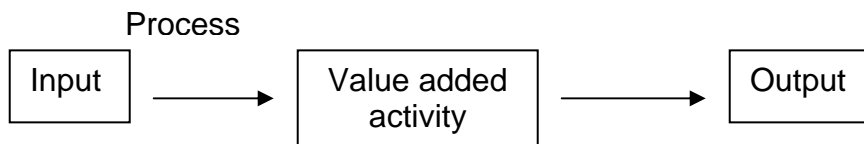
Tools for Statistical Process Control	
Flow Charts	Scatter Diagrams
Pareto Diagrams	Run Charts
Cause and Effect Diagrams	Control Charts
Histograms	Capability Assessment

Flow Charts – Flow charts depict all of the steps of a process. Standard symbols are used to identify the start, finish, processing steps and decision steps. It can be used to simplify a complex process so that it can be analyzed (Figure 1).

Figure 1



Process – For the purpose of this specification, a single process involves the input of a raw material on a production line with a value added activity resulting in a output that can be further processed or meet a customer's need. A complex process involves output being another processes input. The production of ground beef is a complex process.



Pareto Diagrams – The Pareto diagram ranks the importance of different non-conformities. Typically, non-conformities are measured against frequency of occurrence. The Pareto analysis is helpful in identifying and justifying which problems will need to be solved first (see Figure 2)

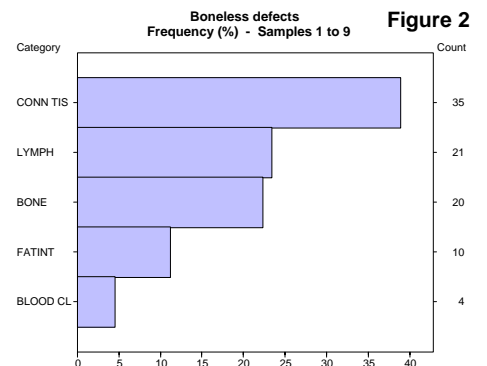


Figure 2

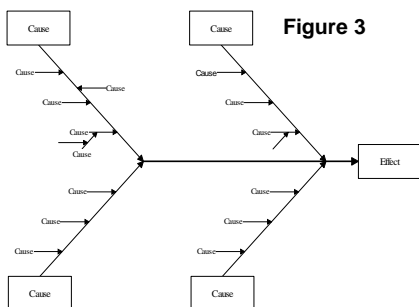
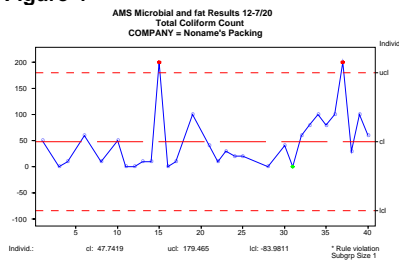


Figure 3

Cause and Effect Diagrams – A cause and effect analysis is used to identify the cause or source of non-conformities. It categorizes the source as derived from impact on a process presented by Human, Machinery, Material, Methods, Environment, and Measurement (Test). The Cause and Effect Diagram will assist in evaluating a process and assigning the appropriate control point (see Figure 3)

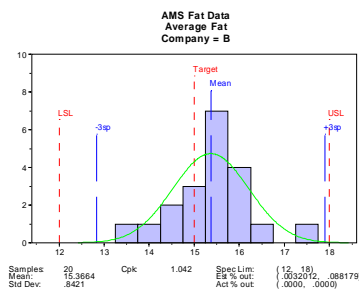
Figure 4



Control Charts – A control chart is a run chart with statistically derived upper and lower control limits (ucl and lcl). The control chart demonstrates if a process is in statistical control. When properly designed, control charts provide an early warning of problems allowing for adjustments to be made before production of non-conforming products. We recommend microbial test results be plotted on control charts for individual measurements with moving range and fat test results be plotted on control charts featuring average and range of the fat test results (See Figure 4).

Upper and lower control limits (ucl and lcl) – Control limits are statistical calculations of the distribution of test results. Upper and lower control limits represent ± 3 standard deviations of the process results (See Figure 4). Data plotted outside the limits represent special causes of variation. A process may be considered “out of statistical control” when results are outside these limits. Upper and lower control limits are not to be confused with specification limits. A supplier wishing to be an eligible participant in the Ground Beef Program shall have a process that is capable of producing within the specification limits.

Upper and lower specification limits (USL and LSL) – Normally, the customer sets the specification limits. The objective of the Ground Beef Purchase Program is to procure from ground beef processors that are statistically capable of meeting the upper specification limits specified within the TRS-GB. The specification limits reflect customer needs (See Figure 5).



Histograms – The histogram shows a pictorial representation of the frequency of distribution of microbial test results over time. Sometimes referred to as process capability charts, histograms compare the distribution of the test results with AMS specification requirements. Use histograms along with control charts to better understand process capability (See Figure 5).

Figure 5

C_{pk} – Process Capability Value (C_{pk}) is a capability analysis index used to determine if a process can meet specification limits. A C_{pk} value of 1 indicates that the process is producing at least 99.73% within the specification limit. C_{pk} values of 1 for many organizations have become the minimum requirement. However, the larger the C_{pk} values the better. C_{pk} differs from other process capability analyses since it considers the process average along with the distribution of test results. Since there is no lower specification limit for USDA microbial requirements, the calculation for C_{pk} will not involve relating the process average with a lower specification limit.

C_{pu} - Process Capability Value (C_{pu}) is the same as C_{pk} except that there is no lower specification limit. The process performance index is correctly known as a Centered Process Capability Upper Specification Limit only (C_{pu}) (See Figure 5).

Process Capability Assessment on 20 consecutive lots – For the purpose of this specification, process capability assessments are conducted on data results from each lot for fat and microbial requirements. A process assessment involves sampling and testing of 20 consecutive lots (which always includes the last recorded result). Information from each lot will be evaluated with information from the preceding 19 lots (i.e., while in process assessment of the first 20 lots, the process was found to be capable, then assessment will continue on lot numbers 2-21). This has often been referred to as a 'Rolling 20'. This assessment takes into account process variations that may be attributed to product, management, sources, and time.

"Cleanup to cleanup" - Part of a HACCP program that the establishment has in place to support statistically distinguishing one portion of production from another. "Cleanup to cleanup" may be an effective means of preventing cross contamination of one part of production to another with *E. coli* O157:H7. However, "cleanup to cleanup" without other supporting documentation may not be adequate to statistically distinguish one portion of production from another. If a sample analysis yields a positive result, any product produced in the same time frame with the same process or equipment is suspect, unless an intervention occurred that would indicate a change in the status of the process/equipment.

Excellent Condition - All product must be in excellent condition; e.g., exposed lean and fat surfaces shall be of a color and bloom normally associated with the class, grade, and cut of meat, and typical of meat which has been properly stored and handled. Cut surfaces and naturally exposed lean surfaces shall show no more than slight darkening or discoloration due to dehydration, aging, and/or microbial activity. The fat shall show no more than very slight discoloration due to oxidation or microbial activity. No odors foreign to fresh meat shall be present. Changes in color and odors characteristically associated with vacuum packaged meat in excellent condition shall be acceptable. Also, product shall show no evidence of mishandling. Beef must be maintained in excellent condition through processing, storage, and transit.

Random Sampling – A process of selecting a sample from a lot whereby each unit in the lot has an equal chance of being selected and is representative of the lot's production.